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Claims 5-6 and 11-12 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office Action states that there are numerous phrases in these claims which are unclear as to how they relate to the other aspects of the claim. Accordingly, in order to further prosecution, the claims have been amended to more specifically cite both what is included in the antisense oligonucleotide and how this oligonucleotide results in the regulation of TNF- $\alpha$  expression. Reconsideration of the rejection is respectfully requested.

Claims 13-16 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office Action states that claims 3, 13, 14 and 16 contain therein numerous phrases which lack antecedent basis. Accordingly, in order to further prosecution, these claims have been amended to provide sufficient antecedent basis for all phrases. Reconsideration of the rejection is respectfully requested.

Claims 15 and 16 stand rejected under 35 U.S.C. § 112, second paragraph, as being incomplete from omitting an essential step. Accordingly, in

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order to further prosecution, such step has been added to the claims and reconsideration of the rejection is respectfully requested.

Claim 5 stands rejected under 35 U.S.C. § 102(e) as being anticipated by the Nyce, et al patent. Reconsideration of the rejection under 35 U.S.C. § 102(e), as anticipated by the Nyce, et al patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In <u>Hybritech Inc. v. Monoclonal Antibodies, Inc.</u>, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In <u>Richardson v. Suzuki Motor Co., Ltd.</u>, 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that claim 5 reads on a synthetic nuclease resistant antisense oligonucleotide for selectively inhibiting human tumor necrosis factor alpha (TNF- $\alpha$ ) comprising an exon targeting sequence flanking donor splice sites. The Office Action states that the claim is interpreted as reading on synthetic antisense oligodeoxynucleotides targeting intron-exon borders of human tumor

necrosis factor alpha (TNF- $\alpha$ ). However, while the Nyce, et al reference does disclose an andenosine  $A_1$  that has an antisense molecule that may target the 5' or 3' intron-exon junctions of the adenosines  $A_1$  receptor, the patent strictly discloses the adenosines  $A_1$  receptor. There is no mention of targeting intron-exon junctions for other genes such as tumor necrosis factor alpha. Furthermore, this patent was filed prior to full characterization of adenosines  $A_1$  receptor. At the time of the filing, delineation of the specific intron-exons was not completely understood. In a paper by Deckert, et al in 1995, there was disclosed further characterization of the adenosines  $A_1$  receptor genes. Since there is no homology between tumor necrosis factor alpha and the  $A_1A$  receptor gene and there is no similarity in function between these two sequences there is no indication that merely the knowledge pertaining to  $A_1A$  would be useful with regard to tumor necrosis factor alpha. Accordingly, reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

Date: January 29, 2001

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

**KOHN & ASSOCIATES** 

Amy E. Rinaldo Registration No. 45,791

30500 Northwestern Hwy. Ste. 410 Farmington Hills, Michigan 48334

(248) 539-5050

## **CERTIFICATE OF TRANSMISSION BY MAIL**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on January 30, 2001.

Marie M. DeWitt